



National Marrow  
Donor Program®

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October 22, 2002

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, Maryland 20852

Dear Dockets Manager:

Enclosed you will find in triplicate copies of the National Marrow Donor Program® latest version of standards, the 18<sup>th</sup> Edition, September 13, 2002, to be filed with docket number 97N-0497. These standards are effective immediately and replace the 17<sup>th</sup> edition, which was provided to the docket at an earlier date.

Please feel free to contact Fran Rabe, Manager of Regulatory Affairs, should you require any additional information as it pertains to the National Marrow Donor Program® standards. (612-362-3490.)

Sincerely,

Fran Rabe  
National Marrow Donor Program  
Manager of Regulatory Affairs

97N-0497

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# **National Marrow Donor Program®**

## **18<sup>th</sup> Edition**

# **Standards**

**September 13, 2002**

### **Notice and Disclaimer NMDP Standards**

These standards set forth only the basic guidelines for programs working through the NMDP to facilitate hematopoietic progenitor cell transplants. These standards do not set forth all that may be required of a facility or individual to conform to federal or state laws or regulations (or non-U.S. equivalent) or the standard of care prevailing in the relevant community. Each facility and individual must determine and follow any additional laws, regulations, practices and procedures that apply in their particular community. The NMDP disclaims all representations or warranties, expressed or implied, that compliance with the NMDP Standards will fulfill the requirements of all applicable federal or state laws and regulations (or their non-U.S. equivalent) or the standard of care prevailing in the relevant community.

# NMDP STANDARDS

## 18<sup>th</sup> Edition, September 13, 2002

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**NATIONAL MARROW DONOR PROGRAM®**  
**DRAFT 18<sup>th</sup> Edition**  
**September 13, 2002**

**1.0000      General**

- 1.1000      Participating programs shall comply with NMDP standards, policies and procedures that include but are not limited to:
  - 1.1100      Completion of all applicable NMDP data forms.
  - 1.1300      Participation in the NMDP Continuous Process Improvement (CPI) program.
  - 1.1400      Provision of annual documentation that NMDP participation and CPI criteria are met.
- 1.2000      Director of a participating program shall be responsible for compliance with these Standards.
- 1.3000      Deviations from these Standards shall be approved according to NMDP policies and procedures.
- 1.4000      Significant changes in personnel, facility or support services shall be reported promptly to the National Coordinating Center.
- 1.5000      Participating programs shall establish a system of strict confidentiality of records to protect the privacy of potential donors, donors and patients.
- 1.6000      Clinical research protocols shall be approved by an Institutional Review Board.

**2.0000      Criteria for Participating Donor Centers**

**2.1000      Facility Characteristics**

- 2.1100      Center shall have demonstrated experience in the recruitment and management of blood, apheresis or marrow donors, including education, counseling, confidentiality issues and medical screening.

- 2.1200 Center shall have adequate resources to support its donor recruitment and management activities.
- 2.1300 Center shall have a designated site for donor management activities, a private space for donor counseling sessions and locked file cabinets for record storage.
- 2.1400 Center shall have an information management system and merge data according to NMDP requirements.
- 2.1500 Center shall have collaborative agreement(s) with participating marrow Collection Center(s).
- 2.1600 Center shall have collaborative agreement(s) with participating or affiliated apheresis Collection Center(s).

**2.2000      *Medical Director***

- 2.2100 Center shall have a medical director who is a licensed physician.
- 2.2200 Center medical director shall be responsible for interpretation of NMDP medical eligibility criteria for donor participation.
- 2.2300 Center medical director shall be responsible for reviewing the medical evaluation of the donor for risks of donation and evidence of disease transmissible by transfusion or transplantation.

**2.3000      *Personnel***

- 2.3100 Center shall designate a coordinator to work with the NMDP.
- 2.3200 Center shall have staff sufficient to manage daily activities.
- 2.3300 Center shall provide staff for each working day and coverage for emergencies.
- 2.3400 Center shall identify a donor advocate and offer the advocate's services to all donors.

## **2.4000      *Support Services***

- 2.4100      Center shall use the following facilities for NMDP activities:
  - 2.4110      HLA typing laboratory(ies) accredited by the American Society for Histocompatibility and Immunogenetics (ASHI) or the European Federation for Immunogenetics (EFI) for techniques required by NMDP.
  - 2.4120      Laboratory (ies) certified by CLIA (or non-US equivalent) for infectious disease marker testing, ABO/Rh typing, red cell antibody screening, and for other tests required by NMDP.
  - 2.4130      Blood Bank licensed or registered by FDA (or non-US equivalent) for collection of autologous blood.
- 2.4200      Center shall provide technical support for computer-related issues.
- 2.4300      Center shall use trained phlebotomists.

## **2.5000      *Policies and Procedures***

- 2.5100      Center shall maintain written standard operating procedures (SOPs) and policies for the recruitment and management of volunteer donors.

## **2.6000      *Applicant Center***

- 2.6100      Applicant shall meet all criteria for participating Donor Centers.
- 2.6200      Applicant shall demonstrate that its donor management abilities, recruitment strategies, and its geographic location or population demographics warrant the establishment of a new center.
- 2.6300      Applicant shall have an HLA-A, B typed file of at least 1000 persons meeting NMDP donor eligibility that could be approached as marrow donors, or be able to show community support for funding the HLA-A, B typing of at least 500 new marrow donors.
- 2.6400      Applicant organization established to recruit donors for a specific patient shall not be eligible for consideration as a Donor Center until the needs of that patient have been resolved.



### **3.0000      Criteria for Participating Donor Recruitment Groups**

#### **3.1000      *Group Characteristics***

- 3.1100      Group shall have permanent or preliminary IRS designation as a 501(c) (3) tax exempt non-profit organization.
- 3.1200      Group shall have a Board of Directors with at least five members including individuals with outreach to the targeted group(s) sought for recruitment.
- 3.1400      Group shall recruit new donors in accordance with priorities of the NMDP.
- 3.1500      Group shall have a written collaborative agreement with each NMDP Donor Center that has agreed to accept the recruited HLA typed donors.
- 3.1600      Groups shall only recruit donors for inclusion in the NMDP.

#### **3.2000      *Medical Director***

- 3.2100      Group shall have access to a Donor Center medical director for assistance with donor eligibility issues.

#### **3.3000      *Personnel***

- 3.3100      Group shall designate a coordinator to work with the NMDP network.
- 3.3200      Group shall have staff sufficient to manage daily activities.

#### **3.4000      *Support Services***

- 3.4100      Group shall use trained phlebotomists.

### **3.5000      *Policies and Procedures***

- 3.5100      Group shall maintain written SOPs and policies for the recruitment of volunteer donors.

### **3.6000      *Applicant Group***

- 3.6100      Applicant shall meet all criteria for a participating Recruitment Group.
- 3.6200      Applicant shall demonstrate that its recruitment strategies and geographic location or population demographics warrant the establishment of a new Recruitment Group.
- 3.6300      Applicant shall have demonstrated experience in donor recruitment activities, including education, counseling, confidentiality issues and medical screening.
- 3.6400      Applicant organization established to recruit donors for a specific patient shall not be eligible for consideration as a Recruitment Group until the needs of the patient have been resolved.
- 3.6500      Applicant shall have recruited 1000 HLA typed donors who have been entered into the NMDP through existing Donor Centers.

## **4.0000      *Criteria for Participating Cord Blood Banks***

### **4.1000      *Facility Characteristics***

- 4.1100      Bank shall have demonstrated experience in the recruitment and management of cord blood collections, including education, counseling, confidentiality issues and medical screening.
- 4.1200      Bank shall have adequate resources to support its recruitment and management activities.
- 4.1300      Bank shall have adequate and secure facilities for processing, storing and retrieving cord blood units and samples.

- 4.1400 Bank shall have a designated site for management activities and locked file cabinets for record storage.
- 4.1500 Bank shall have an information management system and merge data according to NMDP requirements.
- 4.1600 Bank shall have collaborative agreements with facilities collecting cord blood units.

**4.2000      *Medical Director***

- 4.2100 Bank shall have a medical director who is a licensed physician.
- 4.2200 Bank medical director shall be responsible for reviewing the medical evaluation of the donor and biologic mother for evidence of disease transmissible by transfusion or transplantation.
- 4.2300 Bank medical director shall be responsible for the protocols pertaining to: recruitment, informed consent, evaluation and follow-up of the potential donor, and for the collection, transportation, manipulation, cryopreservation and storage of the unit.

**4.3000      *Personnel***

- 4.3100 Bank shall designate a coordinator to work with the NMDP.
- 4.3200 Bank shall have staff sufficient to manage daily activities.
- 4.3300 Bank shall provide staff for each working day and coverage for emergencies.
- 4.3400 Bank shall identify an advocate for the biologic mother of the cord blood donor and offer the advocate's services.
- 4.3500 Bank shall have adequate trained and competent personnel available to perform processing, cryopreservation, storage and retrieval of cord blood units and samples.

#### **4.4000      *Support Services***

- 4.4100      Bank shall use the following facilities for NMDP activities:
  - 4.4110      HLA typing laboratory(ies) accredited by the American Society for Histocompatibility and Immunogenetics (ASHI) or the European Federation for Immunogenetics (EFI) for techniques required by NMDP.
  - 4.4120      Laboratory certified by CLIA (or non-US equivalent) for infectious disease marker testing, ABO/Rh typing, red cell antibody screening, and for other tests required by the NMDP.
  - 4.4130      Cord blood collection sites accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or non-US equivalent.
- 4.4200      Bank shall have technical support for computer-related issues.

#### **4.5000      *Policies and Procedures***

- 4.5100      Bank shall have written procedures for the qualification of cord blood collection facilities and personnel.
- 4.5200      Bank shall have written procedures for recruitment, donor selection, obtaining maternal health and family history, infectious disease marker testing, and for cord blood collection, processing, labeling, storage and transportation.
- 4.5300      Bank shall have written policies and procedures for the release and issue of cord blood units and for the return to inventory of unused cryopreserved units.

#### **4.6000      *Applicant Bank***

- 4.6100      Applicant shall meet all criteria for participating Cord Blood Banks.
- 4.6200      Applicant shall have stored a minimum of 100 cryopreserved cord blood units that each meet NMDP criteria.

## **5.0000      Criteria for Participating Marrow Collection Centers**

### **5.1000      *Facility Characteristics***

- 5.1100      Center shall be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or non-US equivalent.
- 5.1200      Center shall have an experienced team that has collected marrow at least four times in the past year at the center.
- 5.1300      Center shall have adequate resources to support its collection and management activities.
- 5.1400      Center shall have a designated site for management of collection activities.
- 5.1500      Center shall have collaborative agreement(s) with participating Donor Center (s).

### **5.2000      *Medical Director***

- 5.2100      Center shall have a medical director who is a licensed physician.
- 5.2200      Center medical director shall be responsible for reviewing the medical evaluation of the donor for risks of donation and evidence of disease transmissible by transfusion or transplantation.

### **5.3000      *Personnel***

- 5.3100      Collection Center physician performing the marrow collection shall have performed at least 12 prior collections of marrow for transplantation with at least four collections in the previous three years. Any person assisting in the marrow aspiration (physician, nurse, technician) shall have assisted in at least four prior marrow collections for transplantation.
- 5.3200      Center shall provide daily and emergency coverage by designated coordinator(s), sufficient in number to meet the needs of the center's activities.

- 5.3300 Center shall provide anesthesia under supervision by a licensed, board certified anesthesiologist.
- 5.3400 Physician responsible for the marrow collection shall have documented operating room privileges at the Collection Center.

#### **5.4000      *Support Services***

- 5.4100 Center shall have a surgical operating room and a medical intensive care unit.
- 5.4200 Center shall have a flexible schedule for NMDP marrow collections.
  - 5.4210 Donor shall be admitted and discharged from the Collection Center the same day, if the medical status permits.
- 5.4300 Use of allogeneic blood shall be avoided unless deemed medically necessary by the collection physician.
  - 5.4310 Center shall have irradiated blood components available in the event that the use of allogeneic blood cannot be avoided.
- 5.4400 At time of discharge, the center shall provide to the donor post-donation care instructions with contact names and phone numbers.

#### **5.5000      *Policies and Procedures***

- 5.5100 Center shall maintain written SOPs and policies for the collection, testing, labeling, and transport of marrow.
- 5.5200 Center medical director or the physician performing the collection shall perform and/or review a complete medical evaluation of the donor to determine if the donor is an acceptable candidate for marrow collection.
- 5.5300 Center shall verify that the donor has autologous red cell units, appropriate to the anticipated volume of marrow to be collected, available prior to the marrow collection.

5.5400 Center physician responsible for the collection shall be present for the duration of the marrow collection.

5.5500 Center physician shall be responsible for determining that the donor's health is appropriate for discharge.

**5.6000      *Applicant Center***

5.6100 Applicant shall meet all criteria for participating marrow Collection Centers.

5.6200 Applicant shall provide documentation of need from an existing Donor Center.

**6.0000      Criteria for Participating Apheresis Collection Centers**

**6.1000      *Facility Characteristics***

6.1100 Center shall be an institution that is appropriately licensed and/or registered with the Food and Drug Administration or be in compliance with the appropriate non-US equivalent laws and regulations.

6.1200 Center shall have documented experience in the collection of cellular components by apheresis, and shall have performed at least three collections of blood mononuclear cells by apheresis in the past year.

6.1300 Center shall have adequate resources to support its collection and management activities.

6.1400 Center shall have a designated site for management of collection activities.

6.1500 Center shall have collaborative agreement(s) with participating Donor Center(s).

**6.2000      *Medical Director***

6.2100 Center shall have a medical director who is a licensed physician qualified by training and experience to supervise mononuclear cell collections.

- 6.2200 Center medical director shall be responsible for reviewing the medical evaluation of the donor for risks of donation and evidence of disease transmissible by transfusion or transplantation.

**6.3000 Personnel**

- 6.3100 Center physician supervising the apheresis collection shall be qualified by training and experience.
- 6.3200 Center shall designate a coordinator to work with the NMDP.
- 6.3300 Center shall have apheresis collection staff experienced in the collection of blood mononuclear cells and in the management of apheresis donors including those with central venous catheters.
- 6.3400 A licensed physician, qualified by training and experience, shall supervise growth factor administration and donor monitoring.
- 6.3500 A licensed physician qualified by training and experience, shall place any central venous catheters.

**6.4000 Support Services**

- 6.4100 Center shall use the following facilities:
- 6.4110 Laboratory(ies) certified by CLIA (or non-US equivalent) for assessing cell counts, blood chemistries, infectious disease markers, ABO group, Rh type, red cell antibodies, and for other tests required by NMDP.
  - 6.4120 Laboratory with documented proficiency for measuring the quantity of CD 34 positive cells in the component collected.
- 6.4200 Center shall have appropriate apheresis equipment, supplies and pharmaceuticals.
- 6.4300 Center shall provide for emergency care as needed.
- 6.4400 Center shall use JCAHO (or non-US equivalent) accredited hospital for placement of central venous catheters.



## **6.5000      *Policies and Procedures***

- 6.5100      Center shall maintain written SOPs and policies for the collection, testing, storage, labeling, and transport of blood components and for the maintenance of apheresis equipment.
- 6.5200      Responsible physician shall perform and/or review a complete medical evaluation to determine if the donor is an acceptable candidate for apheresis donation.
- 6.5300      Physician experienced in growth-factor administration shall be available throughout growth factor administration and follow up.
- 6.5400      Physician shall be available on-site for the duration of each collection procedure and for follow-up as needed.

## **6.6000      *Applicant Center***

- 6.6100      Applicant shall meet all criteria for participating Apheresis Centers.
- 6.6200      Applicant that is not part of a Donor Center shall provide documentation of need from an existing Donor Center.

## **7.0000      Criteria for Participating Transplant Centers**

### **7.1000      *Facility Characteristics***

- 7.1100      Center shall be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or non-US equivalent.
- 7.1200      Center shall have an experienced team that has performed allogeneic transplants for at least 10 different patients per year.
- 7.1300      Center shall have a designated inpatient unit that minimizes airborne contamination.
- 7.1400      Center shall have a designated area for outpatient evaluation and treatment that reduces the risk of transmission of infectious agents.

- 7.1500 Center with geographically non-contiguous patient care units shall demonstrate functional unity through shared mechanisms such as medical director, coordinator, standard operating policies and procedures, data management, cell processing laboratory, and training of support personnel.
- 7.1510 If the patient care units are located in more than one institution, at least one institution shall satisfy all Transplant Center participation criteria individually. Patient care units at any other institution shall have performed allogeneic transplants for at least four different patients per year.
- 7.1600 Center shall have adequate resources to support its search management activities.
- 7.1700 Center shall have a designated site for management of search activities.

**7.2000 Medical Director**

- 7.2100 Center shall have a medical director who is a licensed physician.
- 7.2200 Center medical director shall have had at least two years experience in an NMDP approved Transplant Center or in a center with publications in peer reviewed journals regarding allogeneic hematopoietic progenitor cell transplantation. One of these years may be a period of training, but there shall have been one year in which the director had primary (attending physician) responsibility for the management of allogeneic transplant recipients.
- 7.2300 Center medical director shall be responsible for search management activities and protecting safety of recipient.

**7.3000 Personnel**

- 7.3100 Center shall have at least two attending physicians who are qualified by training and experience in allogeneic hematopoietic progenitor cell transplantation.

- 7.3200 Center shall provide daily and emergency coverage by designated transplant coordinator(s), sufficient in number to meet the needs of the center's activities.
- 7.3300 Center shall have nurses qualified by training and experience in the care of transplant recipients, sufficient in number to meet patient needs.
- 7.3400 Center shall have sufficient data management personnel to comply with the NMDP policies and procedures.
- 7.3500 Center shall have a patient advocate who is familiar with the center's program and issues of unrelated donor hematopoietic cell transplantation, but is not a member of the transplant team.
- 7.3600 Center shall utilize a person qualified by training and experience in human histocompatibility testing to assist in the selection of unrelated HPC donors.

#### **7.4000      *Support Services***

- 7.4100 Center shall use the following facilities for NMDP activities:
  - 7.4110 HLA typing laboratory (ies) accredited by the American Society for Histocompatibility and Immunogenetics (ASHI) or the European Federation for Immunogenetics (EFI) for techniques required by NMDP.
  - 7.4120 Laboratory (ies) certified by CLIA (or non-US equivalent) for all clinical laboratory tests required by NMDP.
- 7.4200 Center shall use a transfusion service providing 24-hour blood component support for transplant patients, including irradiated blood components and components suitable for CMV-negative recipients.
- 7.4300 Center shall use an experienced hematopoietic progenitor cell processing laboratory.
- 7.4400 Center shall have experienced physicians who provide consultative services in at least the following disciplines: surgery, pulmonary medicine, intensive care, gastroenterology, nephrology, infectious

diseases, cardiology, pathology, psychiatry, and, if applicable, radiation therapy.

- 7.4500 Center shall have sufficient staff from at least the following services: pharmacy, dentistry, dietary, social services and physical therapy.

## **7.5000 Policies and Procedures**

- 7.5100 Center shall maintain written policies and/or SOPs to address at least the following:

- 7.5110 Donor and recipient selection
- 7.5120 Financial approval
- 7.5130 Recipient evaluations
- 7.5140 Infection prevention and control
- 7.5150 Preparative regimen(s)
- 7.5160 Prevention and treatment of graft-versus-host disease
- 7.5170 Hematopoietic progenitor cell infusion
- 7.5180 Blood component transfusion
- 7.5190 Post-transplant care

- 7.5200 Each recipient of hematopoietic progenitor cells from an NMDP donor shall be enrolled in a clinical research protocol or treated according to a written clinical practice guideline.

- 7.5210 Clinical research protocols shall be approved by the center's institutional review board (IRB).

- 7.5211 US Centers shall provide evidence of compliance with the Office of Human Research Protection (OHRP) requirements for a Federalwide Assurance, or have a multiple project assurance or single project assurance that has not expired.

- 7.5212 Non-US centers shall provide evidence of compliance with Independent Ethic Committees (IEC) within their country.
- 7.5220 Written clinical practice guidelines shall include at least the following:
  - 7.5221 Criteria for donor and recipient selection.
  - 7.5222 Procedures for recipient evaluations.
  - 7.5223 Preparative regimen.
  - 7.5224 Procedures for the prevention and treatment of graft-versus-host disease.
  - 7.5225 Procedures for post-transplant care.
- 7.5300 Use of hematopoietic progenitor cells from an NMDP donor shall require provision for the submission of data to the NMDP.
- 7.5310 Unrelated donor transplant recipient shall give written consent for submission of patient data to the NMDP.

#### **7.6000      *Applicant Center***

- 7.6100 Applicant shall meet all criteria for participating Transplant Centers.
- 7.6200 Applicant facility and medical team, including medical director and at least one other physician experienced in allogeneic transplantation shall have been performing transplantation at that site for at least one year.
- 7.6300 Applicant shall have performed at least 10 allogeneic transplants per year during the previous 24 months or 20 allogeneic transplants in the last 12 months.

#### **7.7000      *Patient Advocacy***

- 7.7100 Center shall communicate appropriate information about the progress of a search to patients, families and physicians.

- 7.7200 If a compatible donor is not found, according to the criteria of the transplant center, the patient shall be informed of other options, including:
- 7.7210 Referral to approved transplant centers whose criteria for unrelated transplant are different.
  - 7.7220 Repeated NMDP search results as more donors are added.
  - 7.7230 Search results of other registries.

## **8.0000 Recruitment of HPC Donors**

### **8.1000 Marrow or Apheresis Donor**

- 8.1100 Donor shall be between the ages of 18 and 60.
- 8.1200 Donor shall appear to be in good health.
- 8.1300 Donor shall provide a medical history and acknowledge in writing that the history is accurate.
- 8.1400 Pertinent donor medical history shall be evaluated for acceptance or deferral according to the current NMDP medical eligibility chart and criteria of local Donor Center medical director.
- 8.1500 Donor shall be given educational materials regarding the risks of infectious disease transmission by HPC transplants including high risk behaviors for exposure to Human Immunodeficiency Virus (HIV).
- 8.1600 Donor shall provide informed consent.
  - 8.1610 Donor shall be given a general explanation of the indications for and results of HPC transplantation and reasons for using unrelated donors.
  - 8.1620 Donor shall be given a general description of the donation process and the risks of HPC donation.

- 8.1630 Donor shall be informed that additional HLA testing may be performed on stored samples.
- 8.1640 Donor shall acknowledge in writing that he/she has read and understood the educational material, has been given ample opportunity to ask questions and has had those questions answered satisfactorily.
- 8.1650 Donor shall be informed that he/she has the right to decline or withdraw from NMDP participation at any time without prejudice.
- 8.1700 Donor shall not be coerced to register with NMDP.
- 8.1800 Donor shall be typed for at least HLA A and B by serology or DNA based methods.

#### **8.2000      *Cord Blood Donor***

- 8.2100 Bank shall obtain and document from the biological mother, a family medical history to identify genetic disorders and a personal medical history to identify infections or risk behaviors for infections that are transmissible by transplantation.
- 8.2110 Medical history shall reflect the biological mother's health status at the time of delivery.
- 8.2200 Informed consent shall be obtained from the biological mother for collection, testing, and donation of the cord blood to a Cord Blood Bank for use in unrelated HPC transplantation.
- 8.2210 Biologic mother shall be given a general explanation of the indications for and results of HPC transplantation and reasons for using unrelated donors.
- 8.2220 Biologic mother shall be given a general description of the donation process and the risks of HPC donation.
- 8.2230 Biologic mother shall acknowledge in writing that she has read and understood the educational material, has been given ample opportunity to ask questions and has had those questions answered satisfactorily.

- 8.2300      Biologic mother shall not be coerced to donate cord blood.
- 8.2400      Cord Bank shall test a blood sample from the biological mother of cord blood donor for infectious diseases as defined for marrow or apheresis donor.
  - 8.2410      Blood sample from biological mother of cord blood donor used for infectious disease testing shall be obtained within 7 days prior to or within 7 days after HPC collection.
  - 8.2420      Cord Bank shall inform, counsel and document counseling of biological mother regarding any abnormal findings.
- 8.2500      Medical director or designee shall evaluate medical history and testing results prior to listing the cord blood unit with the NMDP.

## **9.0000      Donation Process**

### **9.1000      *Additional Testing/Information***

#### **9.1100      Patient Directed DR Typing**

- 9.1110      If a stored sample is used for DR testing, the potential donor should be informed that DR typing is in progress and given the opportunity to continue or withdraw.
- 9.1120      If a new blood sample is required, potential donor shall sign a consent form agreeing to provide a blood sample for additional testing.

#### **9.1200      Confirmatory, High-Resolution and Individualized HLA Testing**

- 9.1210      If a stored sample is used for confirmatory, high-resolution or individualized HLA typing, the potential donor shall be informed that the typing is in progress and shall be given the opportunity to continue or withdraw.



- 9.1220 Donor Center shall provide potential donor with educational materials regarding the risks of infectious disease transmission by transplantation.
- 9.1230 Donor shall sign a consent form each time a blood sample is obtained for additional testing.
- 9.1240 Donor Center shall obtain from the donor a medical history that meets NMDP requirements for a marrow or apheresis donor.
  - 9.1241 Donor Center shall keep a written record of the medical history.
  - 9.1242 Medical history indicative of disease shall be evaluated by a physician before acceptance of the donor.
- 9.1250 Testing for evidence of infection due to communicable disease agents shall be performed using screening tests that the Food and Drug Administration (FDA) has approved for such use and shall be performed in accordance with the manufacturer's instructions.

At confirmatory testing, the Donor Center shall perform and/or review the results of the screening tests for evidence of infection due to the following communicable disease agents:

- 9.1251 Human immunodeficiency virus, type 1
- 9.1252 Human immunodeficiency virus, type 2
- 9.1253 Hepatitis B virus
- 9.1254 Hepatitis C virus
- 9.1255 Human T-lymphotropic virus, type 1
- 9.1256 Human T-lymphotropic virus, type 2
- 9.1257 *Treponema pallidum* (syphilis)
- 9.1258 Cytomegalovirus (unless previously documented to be positive)

- 9.1260 At confirmatory testing, the ABO grouping and Rh typing of the potential donor shall be performed at this time if the donor has not been previously typed by the Donor Center.
- 9.1270 At confirmatory testing, the results of the ABO grouping, Rh typing and infectious disease testing shall be reported to the Transplant Center that requested the confirmatory testing sample.
- 9.1271 Donors with a confirmed positive test for HBsAg or HCV shall not be used unless urgent medical need is documented.
- 9.1272 Donors with a confirmed positive test for anti-HIV 1/2 or HIV-1 antigen shall not be used.

**9.1300 Repeat HLA Typing**

- 9.1310 Transplant Center shall repeat HLA-A, B and DR typing of any donor selected for donation.
- 9.1320 Results of the confirmatory HLA typing performed by the Transplant Center shall be sent to the NMDP.
- 9.1330 Transplant Center shall make decisions on donor acceptability as soon as possible so that donors inappropriate for that recipient may be returned to the active search files.

**9.2000 Information Session**

- 9.2100 Information as required by the NMDP shall be provided to the selected potential marrow or apheresis donor before consent is obtained.
- 9.2200 Prospective marrow or apheresis donor shall be informed of at least the following:
- 9.2210 Right to withdraw at anytime, but extreme risk of death for the recipient if the donation is not completed once the preparative regimen is begun.

- 9.2220 Opportunity to discuss his/her decision with a donor advocate.
- 9.2230 Further tests and examinations to be done.
- 9.2240 Magnitude of the time commitment involved in the donation process.
- 9.2250 Possibility that he/she may be asked to provide other blood components or another HPC donation for the same recipient.
- 9.2260 Extent to which the donor's expenses will be compensated and by whom.
- 9.2270 Potential adverse consequences of publicity.
- 9.2280 Pregnancy is an absolute contraindication for marrow donation and growth factor stimulated apheresis.
- 9.2290 Pregnancy is a relative contraindication for unstimulated apheresis donation.
- 9.2300 Prospective marrow donor shall be informed about the procedure of marrow donation and the following risks of marrow donation:
  - 9.2310 Risks of anesthesia.
  - 9.2320 Risks and discomforts of marrow donation including infection, mechanical injury, transfusion and mental/emotional stress.
- 9.2400 Prospective apheresis donor shall be given detailed information about the procedure for mononuclear cell collection by apheresis and the following risks of the collection procedure.
  - 9.2410 Risks and discomforts of the apheresis collection procedure.
  - 9.2420 Possibility of central venous catheter placement, along with its risks and discomforts, if antecubital venous access is unsuitable.
  - 9.2430 Risks and side effects of growth-factor (if applicable).

- 9.2431 Pregnancy is an absolute contraindication to growth-factor administration.

**9.3000      *Medical Evaluation of the Prospective Marrow or Apheresis Donor***

- 9.3100 Donor Center shall provide prospective donor with educational materials regarding the risks of infectious disease transmission by transplantation.
- 9.3200 Medical history
- 9.3210 Donor Center shall obtain from the donor a medical history that meets NMDP requirements.
- 9.3220 Medical history indicative of disease or risk of infectious disease shall be evaluated by a physician to determine the donor's eligibility.
- 9.3300 Medical examination
- 9.3310 Examining physician
- 9.3311 Examining physician shall be a licensed physician and is responsible for protecting the safety of the donor and for delineating conditions in the donor that may be transmissible by transfusion or transplantation.
- 9.3312 Examining physician shall be designated by medical director of Donor or Apheresis Center.
- 9.3313 Examining physician shall not be part of the transplant team of the center performing the transplant.
- 9.3320 Examining physician shall perform and/or evaluate a complete medical history and physical examination to include special notation of the following:
- 9.3321 Pregnancy assessment.

- 9.3322      Deferral from blood donation.
- 9.3323      Contraindications to marrow or apheresis donation.
- 9.3324      Findings that would increase the anesthesia risk for the prospective donor.
- 9.3330      Examining physician shall obtain and evaluate the results of the following tests:
  - 9.3331      Chest X-ray
  - 9.3332      Electrocardiogram
  - 9.3333      Urinalysis
  - 9.3334      Complete blood count
  - 9.3335      Electrolytes
  - 9.3336      Blood urea nitrogen or creatinine
  - 9.3337      Bilirubin
  - 9.3338      Serum protein plus albumin or serum protein electrophoresis
  - 9.3339      Screening for Hemoglobin S, for PBSC donors only
- 9.3340      Examining physician shall evaluate the peripheral venous access for potential apheresis donors.
- 9.3350      Examining physician shall report results of the medical evaluation in writing to the Donor Center including presence or absence of abnormal findings for the specifically mentioned history and physical elements.
- 9.3360      Examining physician shall take an interval history and perform an appropriate physical exam if more than eight weeks have elapsed since the prior evaluation.

9.3370 Final approval of the donor shall not occur until the medical directors of the Collection Center and the Donor Center document that the donor meets the criteria for collection and the donor has signed the "Intent to Donate".

9.3371 Donor Center shall notify the Search Coordinating Unit that the donor is medically eligible and signed the "Intent to Donate".

9.3380 Donor Center shall perform repeat infectious disease testing if previous results were obtained more than 30 days prior to marrow or apheresis donation.

#### **9.4000      *Prospective Donors with Abnormal Findings***

9.4100 Donor Center medical director or designee shall report to the donor any abnormal findings discovered during donor evaluation.

9.4110 Donor shall be counseled about the potential impact of the abnormality.

9.4120 Written documentation of counseling regarding abnormal finding shall be maintained at the Donor Center.

9.4130 Donor has the right to decline donation based on the abnormal findings and keep the reason(s) confidential.

9.4200 Abnormal finding that may increase risk to the donor.

9.4210 Donor Center medical director and Collection Center medical director (or examining physician) shall determine whether an abnormal finding constitutes unacceptable risk to the donor.

9.4220 If the donor agrees to donate, any abnormal finding that may increase risk in the prospective donor shall be reported by the Donor Center to the NMDP.

- 9.4300      Abnormal finding that may increase risk to the recipient.
  - 9.4310      Transplant Center medical director shall determine whether hematopoietic progenitor cells from a donor with an abnormal finding poses unacceptable risk to the recipient.
  - 9.4320      Decision to use hematopoietic progenitor cells from a donor with an abnormal finding that may increase risk to the recipient shall be communicated by the Transplant Center, in writing, to the NMDP.
  - 9.4330      Abnormal finding that may increase recipient risk shall be reported to the recipient, who shall be appropriately counseled as to the potential impact of the abnormality.
    - 9.4331      Written documentation of counseling shall be maintained at the Transplant Center.

**9.5000      *Pre-Collection Communication***

- 9.5100      Marrow or Apheresis Donation
  - 9.5110      Transplant Center shall provide signed acknowledgment to the Coordinating Center that the donor's ABO group and Rh type, degree of HLA match, and test results are acceptable.
  - 9.5120      Initiation of the recipient's preparative regimen shall not occur until the donor has received final approval and infectious disease testing, performed within 30 days of marrow or apheresis donation, and has been reported to the Search Coordinating Unit.
- 9.5200      Marrow Donation
  - 9.5210      Donor Center, Collection Center, and Transplant Center shall agree in writing on the volume and nucleated cell count of marrow to be collected before start of preparative regimen.

- 9.5220 Transplant Center and Collection Center shall agree on the medium, anticoagulant and additives used for collection and transport of marrow.
- 9.5230 Number of nucleated cells to be used for quality assurance and research shall be included and identified separately on the marrow prescription form.
- 9.5240 Donor Center and Collection Center shall agree on the volume of autologous blood to be collected by the Donor Center.

9.5300 Apheresis Donation

- 9.5310 Donor Center, Apheresis Center and Transplant Center shall agree in writing on the following before the start of the recipient's preparative regimen:
  - 9.5311 Volume of whole blood to be processed.
  - 9.5312 Number of apheresis procedures to be performed.
  - 9.5313 Total nucleated cell count.
  - 9.5214 If requested, the total number of CD 34 positive cells to be obtained.

**9.6000      *Pre-Collection Donor Blood Samples***

- 9.6100 Pre-collection donor blood samples in excess of those required for autologous units and samples needed to assess the physical well being of the donor should be:
  - 9.6110 Limited to a maximum of 100 mL in the month prior to marrow donation.
  - 9.6120 Obtained more than 10 days prior to marrow collection.



**9.7000 Subsequent Donor Contacts**

- 9.7100 Following the donation, Donor Center shall evaluate the well-being of the donor in the following manner:
- 9.7110 Telephone call or direct conversation with the donor shall be made within 48 hours of the donation.
  - 9.7120 Contact with the donor shall be repeated between five and seven days after donation.
  - 9.7130 If the donor has any unusual complaints, donor shall be referred to an appropriate source of medical care.
  - 9.7140 Contacts with donor shall continue until the donor is free of complaints related to the HPC collection.
- 9.7200 Subsequent demands on the donor
- 9.7210 Donor shall be asked to provide blood components for the recipient after the transplant only for NMDP approved indications.
  - 9.7220 Donor may be asked to provide an additional marrow or apheresis collection, for the same recipient following NMDP Second Donation Request Policy.
  - 9.7230 Donor should not be asked to donate for a second recipient unless no other equally compatible donor is available and the following conditions are met:
    - 9.7231 At least one year has elapsed between the most recent marrow or apheresis donation for the first recipient and the donor's availability for a second recipient.
    - 9.7232 At least three years have elapsed between a second and third subsequent donation.
  - 9.7240 Donor has the right to refuse consent for any subsequent request.

9.7300 Donor/Recipient Direct Contact

9.7310 Before any direct contact is allowed both donor and recipient or recipient's family shall have signed a consent authorizing release of personal information.

9.7311 Direct contact should not occur until after the first anniversary of the transplant.

**10.0000 Hematopoietic Progenitor Cell (HPC) Collection,  
Transportation, Processing and Labeling**

**10.1000 Marrow Collection**

10.1100 Collection shall be performed only after it has been determined that the intended recipient is suitable for immediate transplant.

10.1110 Collection shall not be requested to store for transplantation at an undetermined future date.

10.1200 Collection shall be performed with a needle designed specifically for marrow collection.

10.1300 Marrow shall only be taken from the iliac crest.

10.1310 Marrow should be taken from the posterior aspect of the iliac crest.

10.1400 Marrow shall be harvested with only the types and amounts of anticoagulants, media and additives agreed on by Transplant and Collection Centers.

10.1500 Marrow should contain the target number of nucleated cells specified by the verified marrow prescription.

10.1510 Collection Center shall count the nucleated cells collected.

- 10.1600 Marrow volume shall not exceed 20 ml/kg donor body weight.
  - 10.1610 Marrow volume should not be so large as to necessitate transfusion of allogeneic blood.
- 10.1700 Marrow shall be filtered during collection using sterile filters made of materials that do not deplete leukocytes.
- 10.1800 Marrow shall be divided into approximately equal portions and packaged in at least two sterile, closed, labeled blood bags approved for HPC storage, each with ports that can be entered aseptically.

**10.2000      *Apheresis Collection (stimulated and unstimulated)***

- 10.2100 Apheresis collection shall be performed using an instrument and software designed for mononuclear cell collection.
- 10.2200 Apheresis collection shall be performed using ACD anticoagulant in a volume sufficient to prevent extracorporeal clotting.
- 10.2300 Total volume of blood processed per collection shall be set by NMDP protocols and procedures.
- 10.2400 After collection, Apheresis Center shall not add anticoagulants, further process or freeze collection without the direct consent of the Transplant Center and approval of the NMDP.
  - 10.2410 Any additions or further processing shall only be performed by Transplant Center or laboratory designated by the Transplant Center.
- 10.2500 Target parameters of apheresis collection shall be specified by prescription.
  - 10.2510 Apheresis Center shall obtain count of nucleated cells collected.
- 10.2600 Growth factor stimulated HPC collection
  - 10.2610 Hematopoietic growth factors shall be given to donors only when approved by the NMDP and the institutional IRB at the recipient and the donor facilities.

- 10.2620 Collection shall be performed only after it is determined that the intended recipient is suitable for immediate transplantation.
- 10.2621 Collection shall not be requested to store for transplantation at an undetermined future date.
- 10.2640 HPCs shall be suspended in sufficient donor plasma to maintain viability of the cells during transport.
- 10.2541 Plasma shall be added to the apheresis collection before the completion of the procedure in an amount agreed upon by the Transplant, Donor and Apheresis Centers.
- 10.2650 HPC collection shall be packaged in a sterile, labeled pack appropriate for HPC storage with a port that can be entered aseptically.

### **10.3000      *Cord Blood Collection and Processing***

- 10.3200 Units shall not be collected and stored with non-human sources of blood or blood derivatives.
- 10.3300 Cord blood unit shall have the following testing:
  - 10.3310 Weight to determine volume
  - 10.3320 Nucleated cell count
  - 10.3330 ABO group and Rh type
  - 10.3340 HLA A, B and DR typing by serology or DNA based methods.
  - 10.3350 Fungal and aerobic bacteria cultures.
  - 10.3351 Antibiotic sensitivities shall be performed on each positive culture and results available prior to listing the cord blood unit with the NMDP.

- 10.3400 Cord blood HPC units shall be stored with at least one cryopreserved product sample available for additional testing.

**10.4000 Marrow or Apheresis Processing**

- 10.4100 Collection Center shall not add anything, process or freeze collection except as requested by the Transplant Center and approved by the NMDP.
- 10.4200 Collection Center shall count the number of nucleated cells in the product.
- 10.4300 Transplant Center shall perform the following testing:
- 10.4310 Repeat ABO grouping and Rh typing of either blood or marrow obtained from the donor at the time of collection
  - 10.4320 Fungal and aerobic bacterial cultures.
    - 10.4321 These cultures are not required for unmanipulated, unstimulated leukapheresis products.
  - 10.4330 Stem cell quantitation by culture and/or surface phenotype if product is intended for engraftment.
- 10.4400 Marrow collection should be infused within 24 hours and apheresis collection should be infused within 48 hours of collection.
- 10.4410 Aliquots of marrow or apheresis HPC collection that are cryopreserved may be infused at a later date.

**10.5000 Labeling and Documentation**

- 10.5100 Label shall contain at least the following:
- 10.5110 Product name
    - 10.5111 If marrow collection “HUMAN HEMATOPOIETIC PROGENITOR CELLS, MARROW.”

- 10.5112 If apheresis HPC collection “HUMAN HEMATOPOIETIC PROGENITOR CELLS, APHERESIS-GROWTH FACTOR STIMULATED”
- 10.5113 If cord blood collection “HUMAN HEMATOPOIETIC PROGENITOR CELLS, CORD BLOOD.”
- 10.5114 If unstimulated leukapheresis collection “HUMAN WHITE BLOOD CELLS, APHERESIS.”
- 10.5120 Donor NMDP identification number.
- 10.5130 Collection date and time.
- 10.5140 Anticoagulant type and volume.
- 10.5150 Intended recipient name, recipient NMDP identification number.
- 10.5160 Recipient’s hospital name and address.
- 10.5170 Name and phone number of hospital staff person designated to accept delivery of the HPC collection.
- 10.5180 “Warning: Contains human tissue for transplantation. Do not delay delivery. Do not X-ray.”
- 10.5190 Biohazard label if donor blood is confirmed positive for anti-HCV or confirmed positive for HBsAg.
- 10.5200 Documents accompanying the product shall indicate at least the following:
  - 10.5210 Donor NMDP identification number.
  - 10.5220 Donor ABO group and Rh type.
  - 10.5230 Results of most recent infectious disease markers required for marrow or apheresis donors.
  - 10.5240 Volume, anticoagulant, diluent and nucleated cell count.
  - 10.5250 Processing description, if applicable.

- 10.5300      Second individual shall verify each item recorded on the label and accompanying documents for accuracy.
- 10.5310      Identity of both individuals verifying information shall be documented.

## **10.6000      *Transportation***

- 10.6100      Each collection bag shall be placed in an outer bag which is sealed to prevent leakage.
- 10.6200      Collection bag(s) shall be enclosed in a rigid container with temperature insulating properties.
- 10.6300      Transportation conditions.
  - 10.6310      Non-cryopreserved products shall be transported at the temperature specified by the Transplant Center or NMDP.
  - 10.6311      Product shall be insulated from direct contact with wet ice or frozen gel packs.
  - 10.6312      Dry ice shall not be used.
  - 10.6320      Cryopreserved HPC collections (storage temperature below -80°C) shall be shipped in a liquid nitrogen “dry shipper” that contains adequate adsorbed liquid nitrogen to maintain temperature at least 48 hours beyond the expected arrival time at the receiving facility.
  - 10.6321      Dry ice shall not be used unless this maintains the indicated storage temperature of the component being shipped.
- 10.6400      Donor Center shall arrange HPC transportation by a means which minimizes transit time.
  - 10.6410      Donor Center shall evaluate alternative means of transportation in case primary means fails.
- 10.6500      If intended recipient has received myeloablative therapy the HPC collection shall be hand carried by a suitably informed courier in the passenger compartment of the transport vehicle.

10.6510 Cryopreserved collection shall be transported in the passenger compartment if permitted by the commercial carrier.

10.6600 Products shall not be passed through X-ray irradiation devices.

## **11.0000 Records and Record Retention**

### **11.1000 General Record Requirements for All Centers.**

- 11.1100 Records shall be created contemporaneously and dated with each step in the NMDP management process.
- 11.1200 Records shall be legible, indelible, complete and retrievable in a reasonable period of time.
- 11.1210 Legible microfilm copies are acceptable.
- 11.1300 Records shall be preserved and protected from accidental or unauthorized destruction or modification.
- 11.1400 All records and communications relating to patients, recipients, donors or potential donors shall be kept strictly confidential.
- 11.1500 Records shall be made available for inspection by authorized individuals.

### **11.2000 Computerized Record Requirements.**

- 11.2100 Center shall maintain the authenticity, integrity and confidentiality of all records, access to which is limited to authorized individuals.
- 11.2200 Written procedures shall be established for record entry, verification and revision.
- 11.2300 If not using NMDP developed computer systems, centers shall document the following:
  - 11.2310 Program development, if done internally.



- 11.2320 Numerical designation of system versions with inclusive dates of use.
- 11.2330 Validation of system functionality (hardware, software and data base).
- 11.2340 Validation and monitoring of data integrity.
- 11.2350 All modifications to the system shall be authorized and documented.
- 11.2400 All centers shall document the following:
  - 11.2410 Installation and upgrades of the system.
  - 11.2420 Training and continuing competency of personnel.
  - 11.2430 Policies and procedures for system maintenance and operations.
  - 11.2440 Ongoing backup procedures.
  - 11.2450 Documented and tested procedures for data restoration.
  - 11.2460 Offsite rotational storage of electronic data records.
- 11.2500 Computer records shall be protected to enable their accurate and ready retrieval throughout the period of required record retention.
- 11.2600 Center shall have an alternative system that permits continuous operation in the event that computerized data are not available.

### **11.3000      *Retention of Records – Indefinite***

#### **11.3100      Donor Records**

- 11.3110 Consent documents for all stages of the search process.
- 11.3120 All health history screenings including infectious disease testing.
  - 11.3121 Reasons for permanent or temporary deferral.

- 11.3122 Records documenting abnormal findings and the notification/counseling of the relevant parties.
- 11.3130 All records pertaining to any donor who donates marrow, cord blood, or peripheral blood progenitor cells.
- 11.3131 Records of adverse reactions and post donation complications and recovery.
- 11.3140 All forms used for data entry.

**11.3200 Recipient Records**

- 11.3210 Consent documents for all stages of the search process.
- 11.3220 Records related to the preliminary search request and recipient HLA typing for all searches that become formal at a given Transplant Center.
- 11.3230 Records indicating the identification numbers of donor(s) requested to participate in specific testing.
- 11.3240 All records pertaining to any search in which the NMDP facilitates the collection.
- 11.3250 Records pertaining to donor abnormal findings and the notification/counseling of relevant parties.
- 11.3260 ABO and Rh typing of the hematopoietic progenitor cells and results of fungal and bacterial cultures of the hematopoietic progenitor cells.
- 11.3270 Informed consent document concerning participation in NMDP research and consent to release personal information (if applicable).
- 11.3280 All forms used for data entry.

**11.4000      *Retention of Records – Finite (retain for a minimum of three years).***

- 11.4100      Recipient search requests and preliminary results of recipient searches that are never formalized.
- 11.4200      Records pertaining to donors that have been deleted from the NMDP and have never donated marrow.
- 11.4300      Records concerning reporting of recipient post transplant clinical data.

**11.5000      *Retention of Records - Transferred Donors.***

- 11.5100      Records, preferably originals, of all transferred donors shall be forwarded to the receiving Donor Center.
- 11.5200      Copies of records pertaining to transferred donors who did not donate may be discarded by the transferring center after three years.

**11.6000      *Retention of Records – Closing Centers.***

- 11.6100      Any center that ceases affiliation with the Program shall make provisions for maintenance or transfer of records to a facility designated by the closing center and approved by the NMDP.